**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 03N–0038]**

# Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device User Fee Cover Sheet; Form FDA 3601

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written or electronic comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Medical Device User Fee Cover Sheet; Form FDA 3601**

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to: (1) Determine whether a fee is required for review of an application, (2) determine the amount of the fee required, and (3) account for and track user fees. The form provides a cross-reference of the fees submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

Respondents to this collection of information are device manufacturers. Based on FDA's database system, there are an estimated 5,000 manufacturers of products subject to MDUFMA. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions

received by FDA in fiscal year 2002. CDRH estimates 5,000 annual responses that include the following: 50 premarket approval applications, 4,400 premarket notifications, 30 modular premarket applications, 1 product development protocol, 1 premarket report, 20 panel track supplements, 150 real-time supplements, and 348 180-day supplements. CBER estimates 50 annual responses that include the following: 2 premarket approval applications, 3 biologics license applications, 30 premarket notifications, 10 modular premarket applications, and 5 180-day supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of February 26, 2003 (68 FR 8907) FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Form | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| FDA 3601 | 5,000 | 1 | 5,000 | .30 | 1,500 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 15, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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